

1 What is claimed is:

2

3 1. In a stented graft that can alternately include a compact configuration having  
4 a first diameter and an expanded configuration having a greater diameter,  
5 comprising, in combination:

6 ☐ at least one stent formed in a generally cylindrical shape having an  
7 outer surface and a hollow bore extending longitudinally therethrough,  
8 wherein said stent can alternately exist in a compact configuration  
9 having a first diameter, and an expanded configuration having a  
10 greater diameter and a plurality of lateral openings; and,

11 ☐ a flexible, porous, biocompatible tubular elastomer covering having a  
12 first end, a second end, an outer surface and a hollow bore that  
13 extends longitudinally therethrough to define an inner surface;

14 said stent being deployed coaxially within said hollow bore of said covering  
15 such that said inner surface of said tubular covering is in contact with said  
16 outer surface of said stent;

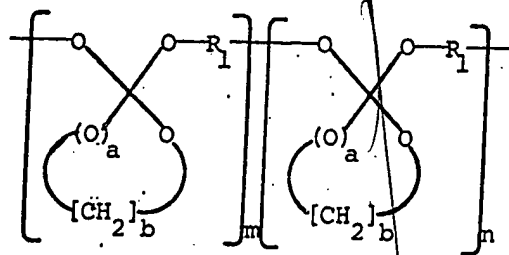
17 the improvement wherein said stent is coated with a coat comprising a  
18 composite of at least one polymer and at least one therapeutic substance to  
19 form a drug eluting stented graft.

20

21 2. The drug eluting stented graft of claim 1, wherein said at least one  
22 polymer is a biocompatible, pharmaceutically acceptable, bioerodible  
23 polymer.

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- 1 3. The drug eluting stented graft of claim 1, wherein said at least one  
2 polymer is a polyester.
- 3
- 4 4. The drug eluting stented graft of claim 1, wherein said at least one  
5 therapeutic agent is selected from the group consisting of antiplatelet  
6 agents, anticoagulant agents, antimetabolic agents, vasoactive agents,  
7 nitric oxide releasing agents, anti-inflammatory agents, antiproliferative  
8 agents, antisense agents, pro-endothelial agents, anti-migratory agents,  
9 antimicrobial agents, selective gene delivery vectors, sirolimus,  
10 actinomycin-D and paclitaxel.
- 11
- 12 5. The drug eluting stented graft of claim 4, wherein said selective gene  
13 delivery vectors are Semliki Forest Virus (SMV) adapted to deliver  
14 restenosis preventing genes.
- 15
- 16 6. The drug eluting stented graft of claim 1, wherein said at least one  
17 polymer is a hydrophobic, bioerodible, copolymer comprising mers I and  
18 II according to the following formula:

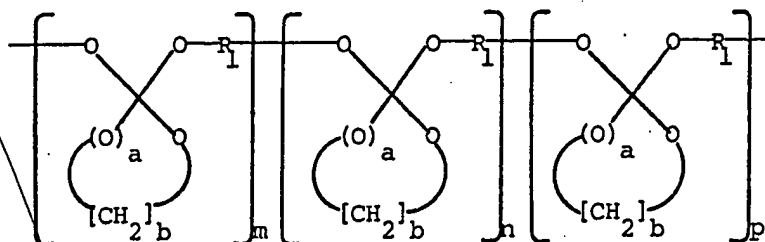


23 wherein:

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- 1       □ R<sub>1</sub> is a member selected from the group consisting of alkylene  
2       of 1 to 10 carbons; alkenylene of 2 to 10 carbons; alkyleneoxy of 2 to 6  
3       carbons; cycloalkylene of 3 to 7 carbons; cycloalkylene of 3 to 7 carbons  
4       substituted with a member selected from the group consisting of alkyl of  
5       1 to 7 carbons, an alkoxy of 1 to 7 carbons, an alkylene of 1 to 10  
6       carbons, and an alkenyl of 2 to 7 carbons; cycloalkenylene of 4 to 7  
7       carbons; cycloalkenylene of 4 to 7 carbons substituted with an alkyl of 1  
8       to 7 carbons, an alkoxy of 1 to 7 carbons, an alkylene of 1 to 10 carbons,  
9       and an alkenyl of 2 to 7 carbons; arylene; and arylene substituted with an  
10      alkyl of 1 to 7 carbons, an alkoxy of 1 to 7 carbons, an alkylene of 1 to  
11      10 carbons, an alkenyl of 2 to 7 carbons; and wherein a is 0 to 1; b is 2  
12      to 6; m is greater than 10; n is greater than 10; and at least one of  
13      R<sub>1</sub>, a, and b in mer I is different than R<sub>1</sub>, a, and b in mer II; and wherein:  
14  
15      □ said composite of at least one polymer and at least one therapeutic  
16      substance when in operation bioerodes and releases said at least one  
17      therapeutic substance at a rate selected from (1) a zero order rate,(2) a  
18      continuous rate, and (3) a variable rate, which rate is produced by  
19      preselecting said composite of at least one polymer and at least one  
20      therapeutic substance, and said elastomer to give the desired result.  
21

7. The drug eluting stented graft of claim 1, wherein said at least one polymer is a hydrophobic, bioerodible, terpolymer comprising mers I, II, and III according to the following formula:



wherein:

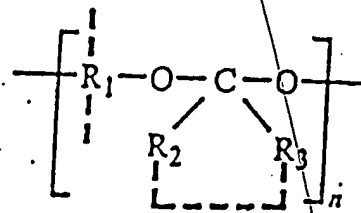
- R<sub>1</sub> is a member selected from the group consisting of alkylene of 1 to 10 carbons; alkenylene of 2 to 10 carbons; alkyleneoxy of 2 to 6 carbons; cycloalkylene of 3 to 7 carbons; cycloalkylene of 3 to 7 carbons substituted with a member selected from the group consisting of alkyl of 1 to 7 carbons, alkoxy of 1 to 7 carbons, an alkylene of 1 to 10 carbons, and an alkenyl of 2 to 7 carbons; cycloalkenylene of 4 to 7 carbons; cycloalkenylene of 4 to 7 carbons substituted with an alkyl of 1 to 7 carbons, an alkoxy of 1 to 7 carbons, an alkylene of 1 to 10 carbons, and an alkenyl of 2 to 7 carbons; arylene; and arylene substituted with an alkyl of 1 to 7 carbons, an alkoxy of 1 to 7 carbons, an alkylene of 1 to 10 carbons, an alkenyl of 2 to 7 carbons; and
- wherein a is 0 to 1; b is 2 to 6; m is greater than 10; n is greater than 10; p is greater than 10; and at least one of R<sub>1</sub>, a, and b in mers I, II and III is different than R<sub>1</sub>, a, and b in mers I, II and III; and wherein:

□ said composite of at least one polymer and at least one therapeutic substance when in operation bioerodes and releases said at least one therapeutic substance at a rate selected from (1) a zero order rate, (2) a continuous rate, and (3) a variable rate, which rate is produced by preselecting said composite of said at least one polymer and said at least one therapeutic substance, and said elastomer to give the desired result.

8. The drug eluting stented graft of claim 1, wherein:

- a multiplicity of microcapsules is dispersed within said at least one polymer, wherein said microcapsules have a wall formed of a drug release rate controlling material;
- said at least one therapeutic substance is contained within said multiplicity of microcapsules; and,

□ said at least one polymer has the formula:



wherein R<sub>1</sub> is a member selected from the group of divalent, trivalent and tetravalent radicals consisting of alkylene of 1 to 10 carbons; alkenylene of

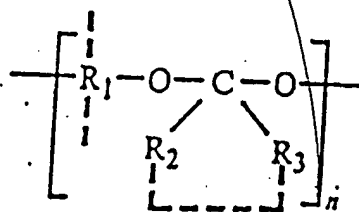
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2 to 10 carbons; alkyleneoxy of 2 to 6 carbons; cycloalkylene of 3 to 7 carbons; cycloalkylene of 3 to 7 carbons substituted with an alkyl of 1 to 7 carbons, alkoxy of 1 to 7 carbons, an alkylene of 1 to 10 carbons, and an alkenyl of 2 to 7 carbons; cycloalkenylene of 4 to 7 carbons cycloalkenylene of 4 to 7 carbons substituted with an alkyl of 1 to 7 carbons, an alkoxy of 1 to 7 carbons, an alkylene of 1 to 10 carbons, and an alkenyl of 2 to 7 carbons; arylene; and arylene substituted with an alkyl of 1 to 7 carbons, an alkoxy of 1 to 7 carbons, and an alkenyl of 2 to 7 carbons;  $R_2$  and  $R_3$  are selected from the group consisting of alkyl of 1 to 7 carbons; alkenyl of 2 to 7 carbons; alkoxy of 1 to 7 carbons; alkenyloxy of 2 to 7 carbons; alkylene of 2 to 6 carbons; alkenylene of 3 to 6 carbons; alkyleneoxy of 2 to 6 carbons; alkenyleneoxy of 3 to 6 carbons; aryloxy; aralkyleneoxy of 8 to 12 carbons; aralkenyleneoxy of 8 to 12 carbons; oxa;  $OR_1O$  with  $R_1$  as defined above; a heterocyclic ring of 5 to 8 carbon and oxygen atoms formed when  $R_2$  and  $R_3$  are taken together; a heterocyclic ring of 5 to 8 carbon and oxygen atoms substituted with an alkyl of 1 to 7 carbons, an alkoxy of 1 to 7 carbons and alkenyl of 2 to 7 carbons formed when  $R_2$  and  $R_3$  are taken together; a fused polycyclic ring of 8 to 12 carbon and oxygen atoms formed when  $R_2$  and  $R_3$  are taken together; a fused polycyclic ring of 8 to 12 carbon and oxygen atoms substituted with an alkyl of 1 to 7 carbons; an alkoxy of 1 to 7 carbons and an alkenyl of 2 to 7 carbons; and wherein at least one of said  $R_2$  and  $R_3$  is a member selected from the group consisting of alkoxy, alkenyloxy and  $OR_1O$ ;  $R_2$

1 and R<sub>3</sub> when taken together are a member selected from the group of  
2 heterocyclic and fused polycyclic rings having at least one oxygen atom in  
3 the ring; and wherein n is greater than 10;  
4 so that, in operation, said polymer and said microcapsules bioerode at a  
5 controlled and continuous rate over a prolonged period of time, thereby releasing  
6 said at least one therapeutic substance at a controlled and continuous rate over  
7 a prolonged period of time.

8  
9 9. The drug eluting stented graft of claim 1, wherein:

- 10 □ said coat further comprises at least a first layer and a second layer,  
11 wherein said first layer comprises said at least one therapeutic  
12 substance and at least a first polymer, and said second layer  
13 comprises said at least one therapeutic substance and at least a  
14 second polymer, wherein at least one of said first polymer and said  
15 second polymer are selected from the group consisting of polymers of  
16 the formula:



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1 wherein  $R_1$  is a member selected from the group of divalent, trivalent and  
2 tetravalent radicals consisting of alkylene of 1 to 10 carbons; alkenylene of 2 to  
3 10 carbons; alkyleneoxy of 2 to 6 carbons; cycloalkylene of 3 to 7 carbons;  
4 cycloalkylene of 3 to 7 carbons substituted with an alkyl of 1 to 7  
5 carbons, alkoxy of 1 to 7 carbons, alkylene of 1 to 10 carbons, and an  
6 alkenyl of 2 to 7 carbons; cycloalkenylene of 4 to 7 carbons;  
7 cycloalkenylene of 4 to 7 carbons substituted with an alkyl of 1 to 7  
8 carbons, an alkoxy of 1 to 7 carbons, an alkylene of 1 to 10 carbons, and  
9 an alkenyl of 2 to 7 carbons; arylene; and arylene substituted with an  
10 alkyl of 1 to 7 carbons, an alkoxy of 1 to 7 carbons, and an alkenyl of 2  
11 to 7 carbons;  $R_2$  and  $R_3$  are selected from the group consisting  
12 of alkyl of 1 to 7 carbons; alkenyl of 2 to 7 carbons; alkoxy of 1 to 7  
13 carbons; alkenyloxy of 2 to 7 carbons; alkylene of 2 to 6 carbons;  
14 alkenylene of 3 to 6 carbons; alkyleneoxy of 2 to 6 carbons; alkenyleneoxy  
15 of 3 to 6 carbons; aryloxy; aralkyleneoxy of 8 to 12 carbons;  
16 aralkenyleneoxy of 8 to 12 carbons; oxa;  $O R_1 O$  with  $R_1$  as  
17 defined above; a heterocyclic ring of 5 to 8 carbon and oxygen atoms  
18 formed when  $R_2$  and  $R_3$  are taken together; a heterocyclic ring of  
19 5 to 8 carbon and oxygen atoms substituted with an alkyl of 1 to 7  
20 carbons; an alkoxy of 1 to 7 carbons and an alkenyl of 2 to 7 carbons  
21 formed when  $R_2$  and  $R_3$  are taken together; a fused polycyclic  
22 ring of 8 to 12 carbon and oxygen atoms formed when  $R_2$  and  $R_3$   
23 are taken together; a fused polycyclic ring of 8 to 12 carbon and oxygen



1 atoms substituted with an alkyl of 1 to 7 carbons, an alkoxy of 1 to 7  
2 carbons and an alkenyl of 2 to 7 carbons; and wherein at least one of said  
3  $R_2$  and  $R_3$  is a member selected from the group consisting of alkoxy, alkenyloxy  
4 and  $OR_1O$ ;  $R_1$  and  $R_3$  when taken together are a member selected from the  
5 group of heterocyclic and fused polycyclic rings having at least one oxygen atom  
6 in the ring; and wherein is greater than 10;  
7 so that when in operation, said layers bioerode at a controlled and continuous  
8 rate over a prolonged period of time, thereby releasing said at least one  
9 therapeutic substance at a controlled and continuous rate over a prolonged  
10 period of time.

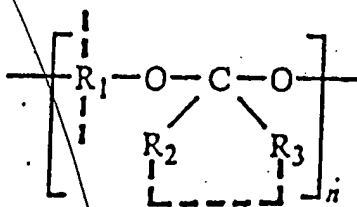
11  
12 10. The drug eluting stented graft of claim 9, wherein said first polymer is a  
13 pharmaceutically acceptable biocompatible non-bioerodible polymer that  
14 sequesters an agent for brachytherapy.

15  
16 11. The drug eluting stented graft of claim 10, wherein said agent for  
17 brachytherapy is selected from the group consisting of palladium-103 ( $^{103}\text{Pd}$ ),  
18  $^{192}\text{Ir}$ ,  $^{32}\text{P}$ ,  $^{188}\text{Re}$ , and Sr/Y90 source trains.

19  
20 12. The drug eluting stented graft of claim 1, wherein:

- 21 ☐ a multiplicity of discrete, closed cells exists within said at least one  
22 polymer, said cells having a wall formed and defined by said at least  
23 one polymer;

□ said at least one polymer has the formula:



wherein  $R_1$  is a member selected from the group of divalent, trivalent and tetravalent radicals consisting of alkylene of 1 to 10 carbons; alkenylene of 2 to 10 carbons; alkyleneoxy of 2 to 6 carbons; cycloalkylene of 3 to 7 carbons; cycloalkylene of 3 to 7 carbons substituted with an alkyl of 1 to 7 carbons, alkoxy of 1 to 7 carbons, an alkylene of 1 to 10 carbons, and an alkenyl of 2 to 7 carbons; cycloalkenylene of 4 to 7 carbons; cycloalkenylene of 4 to 7 carbons substituted with an alkyl of 1 to 7 carbons, an alkoxy of 1 to 7 carbons, an alkylene of 1 to 10 carbons, and an alkenyl of 2 to 7 carbons; arylene; and arylene substituted with an alkyl of 1 to 7 carbons, an alkoxy of 1 to 7 carbons, and an alkenyl of 2 to 7 carbons;  $R_2$  and  $R_3$  are selected from the group consisting of alkyl of 1 to 7 carbons; alkenyl of 2 to 7 carbons; alkoxy of 1 to 7 carbons; alkenyloxy of 2 to 7 carbons; alkylene of 2 to 6 carbons; alkenylene of 3 to 6 carbons; alkyleneoxy of 2 to 6 carbons; alkenyleneoxy of 3 to 6 carbons; aryloxy; aralkyleneoxy of 8 to 12 carbons; aralkenyleneoxy of 8 to 12 carbons; oxa;

OR<sub>1</sub>O with R<sub>1</sub> as defined above; a heterocyclic ring of 5 to 8 carbon and oxygen atoms formed when R<sub>2</sub> and R<sub>3</sub> are taken together; a heterocyclic ring of 5 to 8 carbon and oxygen atoms substituted with an alkyl of 1 to 7 carbons, an alkoxy of 1 to 7 carbons and an alkenyl of 2 to 7 carbons formed when R<sub>2</sub> and R<sub>3</sub> are taken together; a fused polycyclic ring of 8 to 12 carbon and oxygen atoms formed when R<sub>2</sub> and R<sub>3</sub> are taken together; a fused polycyclic ring of 8 to 12 carbon and oxygen atoms substituted with an alkyl of 1 to 7 carbons, an alkoxy of 1 to 7 carbons and an alkenyl of 2 to 7 carbons; and wherein at least one of said R<sub>2</sub> and R<sub>3</sub> is a member selected from the group consisting of alkoxy, alkenyloxy and OR<sub>1</sub>O; R<sub>2</sub> and R<sub>3</sub> when taken together are a member selected from the group of heterocyclic and fused polycyclic rings having at least one oxygen atom in the ring; and wherein n is greater than 10;

□ wherein said at least one therapeutic substance dissolved in a pharmaceutically acceptable carrier that is a solvent for said at least one therapeutic substance and a nonsolvent for said at least one polymer is contained within said multiplicity of discrete, closed cells; so that, when in operation, said at least one polymer is capable of bioeroding at a controlled and continuous rate over a prolonged period of time, thereby releasing said at least one therapeutic substance at a controlled and continuous rate over a prolonged period of time.

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1 13. The drug eluting stented graft of claim 1, wherein said stent comprises a  
2 plurality of elements, wherein each said element comprises an undulating  
3 linear shape formed into a generally cylindrical configuration having a cylinder  
4 axis generally aligned on the axis of said hollow bore, and wherein each said  
5 element is connected to an adjacent neighbor element by at least one linear  
6 connector.

7  
8 14. The drug eluting stented graft of claim 1, wherein said plurality of elements  
9 comprises a spiral.

10  
11 15. The drug eluting stented graft of claim 1, wherein at least one said connector  
12 is substantially circumferentially offset from an adjacent neighbor connector.

13  
14 16. The drug eluting stented graft of claim 15, wherein said circumferentially  
15 offset connectors form a helical array.

16  
17 17. The drug eluting stented graft of claim 1, wherein at least one said connector  
18 is not substantially circumferentially offset from an adjacent neighbor  
19 connector.

20  
21 18. The drug eluting stented graft of claim 1, wherein said undulating linear shape  
22 is a generally zigzag shape comprising a plurality of zigs having tips and a  
23 plurality of zags having tips, wherein said tip of each said zig of each element

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1 and the nearest said tip of each said zig of an adjacent neighbor element  
2 generally lie in a plane passing through the axis of said hollow bore, and  
3 wherein said tip of at least one said zig of each element and at least one said  
4 nearest said tip of a zig of an adjacent neighbor are connected by one said  
5 linear connector.

6  
7 19. The drug eluting stented graft of claim 1, wherein said undulating linear shape  
8 is a sinusoidal shape having a plurality of peaks and a plurality of valleys,  
9 wherein each said peak of each element and each said valley of an adjacent  
10 neighbor lie generally in a common plane passing through the axis of said  
11 hollow bore, and wherein at least one said peak of each element and said  
12 valley of an adjacent neighbor lying generally in said common plane are  
13 connected by one said linear connector.

14  
15 20. The drug eluting stented graft of claim 1, wherein each said linear connector  
16 has a length dimension generally parallel to the axis of said hollow bore, and  
17 a width and depth dimension, and wherein said length dimension is greater  
18 than said width dimension and said length dimension is greater than said  
19 depth dimension.

20  
21 21. The drug eluting stented graft of claim 20, wherein said length dimension is  
22 about 3 to 10 times greater than said width dimension, and said length  
23 dimension is about 3 to 10 times greater than said depth dimension.

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2 22. The drug eluting stented graft according to claim 1, wherein said stent and  
3 said elastomer are anchored to each other by means for anchoring.

4

5 23. The tubular drug eluting stented graft according to claim 22, wherein said  
6 means for anchoring comprise protrusions of said covering that fixedly  
7 protrude into said lateral openings in said stent.

8

9 24. The drug eluting stented graft of claim 1 wherein said elastomer covering is  
10 formed of an elastomer selected from the group consisting of  
11 polytetrafluoroethylene, fluorinated ethylene propylene,  
12 polytetrafluoroethylene-perfluoroalkyl vinyl ether copolymer, polyvinyl  
13 chloride, polypropylene, polyethylene terephthalate, broad fluoride; and, other  
14 biocompatible plastics.

15

16 25. The drug eluting stented graft of claim 1 wherein said elastomer covering is  
17 formed of expanded, sintered PTFE tape, said tape having been wound about  
18 the outer surface of said stent to create said covering thereon.

19

20 26. The drug eluting stented graft of claim 24, wherein said  
21 polytetrafluoroethylene is expanded polytetrafluoroethylene having fibrils.

22

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1 27. The drug eluting stented graft of claim 26, wherein said fibrils measure up to  
2 about 300  $\mu$  in length.

3  
4 28. The drug eluting stented graft of claim 26, wherein said fibrils measure up to  
5 about 200  $\mu$  in length.

6  
7 29. The drug eluting stented graft of claim 26, wherein said fibrils measure up to  
8 about 100  $\mu$  in length.

9  
10 30. The drug eluting stented graft of claim 26, wherein said fibrils measure up to  
11 about 50  $\mu$  in length.

12  
13 31. The drug eluting stented graft of claim 26, wherein said fibrils measure up to  
14 about 5  $\mu$  in length.

15  
16 32. The drug eluting stented graft of claim 25 wherein said tape has a width of  
17 less than about 1 inch.

18  
19 33. The drug eluting stented graft of claim 25 wherein said tape has a thickness  
20 of less than 0.015 inch (0.038 cm.) and wherein said tape is wound about  
21 said stent in overlapping fashion, such that said elastomer covering  
22 comprises 1 to 10 layers of said tape.

23

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1 34. The drug eluting stented graft of claim 25 wherein said tape is helically  
2 wrapped about said stent.

3  
4 35. The drug eluting stented graft of claim 25 wherein said tape has a width of 0.5  
5 inches (1.27 cm), and wherein said tape is helically wrapped such that 6-8  
6 revolutions of tape are applied per longitudinal inch (2.54 cm.) of said drug  
7 eluting stented graft.

8  
9 36. The drug eluting stented graft of claim 25 wherein said tape is helically  
10 wrapped alternately in a first direction and then in the opposite direction.

11  
12 37. The drug eluting stented graft of claim 36 further comprising 8 layers of said  
13 tape.

14  
15 38. The drug eluting stented graft of claim 1 wherein said stent is a self-  
16 expanding stent.

17  
18 39. The drug eluting stented graft of claim 38, wherein said self-expanding stent  
19 comprises a shape memory alloy that can alternately exist in a first and a  
20 second crystalline state, wherein said stent assumes a radially expanded  
21 configuration when said shape memory alloy is in said first crystalline state,  
22 and a radially compact configuration when said shape memory alloy is in said  
23 second crystalline state.

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2 40. The drug eluting stented graft of claim 1 wherein said stent is a pressure-  
3 expandable stent.

4

5 41. The drug eluting stented graft of claim 1 wherein said stent is formed of a  
6 metal alloy comprising at least two elements selected from the group  
7 consisting of iron, cobalt, chromium, nickel, titanium, niobium, and  
8 molybdenum.

9

10 42. The drug eluting stented graft of claim 39 wherein said shape memory alloy  
11 comprises at least about 51% to about 59% nickel and the remainder  
12 comprising titanium.

13

14 43. The drug eluting stented graft of claim 39 wherein said shape memory alloy  
15 comprises about 0.25% chromium, at least about 51% to about 59% nickel,  
16 and the remainder comprising titanium.

17

18 44. The drug eluting stented graft of claim 1 wherein said covering has a  
19 thickness of less than 0.1 inch (0.25 cm.).

20

21 45. The drug eluting stented graft of claim 25 wherein said PTFE tape has a  
22 thickness of less than 0.015 inches (0.038 cm.), said tape being wrapped  
23 about said stent in overlapping fashion so as to form said covering.

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2 46. The drug eluting stented graft of claim 25 wherein said PTFE tape has a  
3 density of less than 1.6 g/cc.

4

5 47. The drug eluting stented graft of claim 25 wherein said covering has a  
6 thickness of less than 0.1 inch (0.25 cm.) and said PTFE tape has a density  
7 of less than 1.6 g/cc.

8

9 48. The drug eluting stented graft of claim 1 wherein said composite coating was  
10 applied to said stent by the steps of:

- 11 ☐ immersing said stent in a liquid dispersion of said composite;
- 12 ☐ removing said stent from said liquid dispersion of said composite; and,
- 13 ☐ drying said liquid dispersion of said composite that has remained on  
14 said stent,

15 whereby said composite coating is formed on said stent.

16

17 49. The drug eluting stented graft of claim 1 wherein said composite coating is  
18 formed by electron beam deposition.

19

20 50. The drug eluting stented graft of claim 1 wherein said tubular covering is  
21 adherent to said coat.

22

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1 51. A method for the treatment of cardiovascular disease, comprising implanting  
2 the drug eluting stented graft of claim 1 in a patient in need of such treatment  
3 wherein said implantation is effective to ameliorate one or more of the  
4 symptoms of said cardiovascular disease.

5  
6 52. An article of manufacture, comprising packaging material and the drug eluting  
7 stented graft of claim 1 contained within the packaging material, wherein said  
8 drug eluting stented graft is effective for implantation in a patient afflicted with  
9 cardiovascular disease, and the packaging material includes a label that  
10 indicates that said device is effective for said implantation.

11  
12 53. In a tubular stented graft which is alternately deployable in a radially compact  
13 configuration having a first diameter and a radially expanded configuration  
14 having a second diameter, said stented graft comprising:

- 15 • a stent comprising:
- 16 □ at least one member formed in a generally cylindrical shape having
  - 17 an outer surface and a hollow bore which extends longitudinally
  - 18 therethrough to define an inner surface;
  - 19 □ said stent being initially radially collapsible to a diameter which is
  - 20 substantially equal to said first diameter of the stented graft, and
  - 21 subsequently radially expandable to a diameter which is
  - 22 substantially equal to said second diameter of the stented graft;
  - 23 and,

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- 1       □ a plurality of lateral openings existing in said stent when said stent is at  
2       its radially expanded second diameter;
- 3       • a continuous, tubular PTFE covering formed on said stent, said PTFE  
4       covering comprising:
- 5       □ a tubular inner base graft formed of expanded, sintered PTFE, said  
6       tubular base graft having an outer surface and an inner surface, said  
7       tubular base graft being deployed coaxially within the hollow bore of  
8       said stent such that the outer surface of the tubular base graft is in  
9       contact with the inner surface of the stent, and the inner surface of said  
10      tubular base graft thereby defining a luminal passageway through the  
11      stented graft; and,
- 12      □ a tubular outer layer formed of expanded, sintered PTFE tape which  
13      has a width of less than about 1 inch, said tape having been wound  
14      about the outer surface of said stent to create said tubular outer layer  
15      thereon, such that said stent is captured between said outer layer and  
16      said tubular base graft;
- 17      said tubular outer layer being attached to said tubular base graft, through  
18      said lateral openings in said stent, to thereby form an integrally stented,  
19      continuous PTFE tube which is alternately disposable in said radially  
20      compact configuration of said first diameter and said radially expanded  
21      configuration of said second diameter;

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the improvement wherein said stent is coated with a coat comprising a composite of at least one polymer and at least one therapeutic substance to form a drug eluting stented graft.

54. The drug eluting stented graft of claim 53, wherein said at least one polymer is a biocompatible, pharmaceutically acceptable, bioerodible polymer.

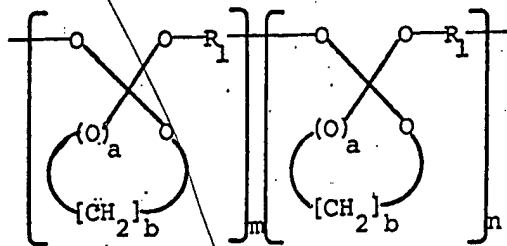
55. The drug eluting stented graft of claim 53, wherein said at least one polymer is a polyester.

56. The drug eluting stented graft of claim 53, wherein said at least one therapeutic agent is selected from the group consisting of antiplatelet agents, anticoagulant agents, antimetabolic agents, antisense agents, vasoactive agents, nitric oxide releasing agents, anti-inflammatory agents, antiproliferative agents, pro-endothelial agents, anti-migratory agents, antimicrobial agents, selective gene delivery vectors, sirolimus, actinomycin-D and paclitaxel.

57. The drug eluting stented graft of claim 56, wherein said selective gene delivery vectors are Semliki Forest Virus (SMV) adapted to deliver restenosis preventing genes.

**0007867 - J. Edgar Hoover**

58. The drug eluting stented graft of claim 53, wherein said at least one polymer is a hydrophobic, bioerodible, copolymer comprising mers I and II according to the following formula:

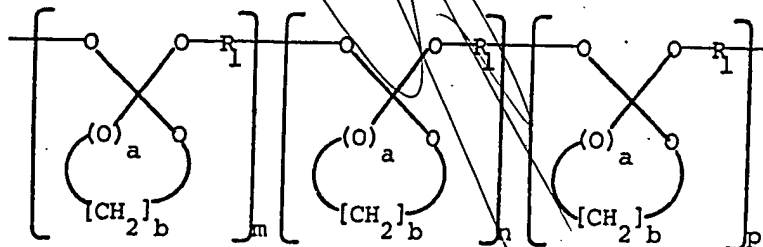


wherein:

- R<sub>1</sub> is a member selected from the group consisting of alkylene of 1 to 10 carbons; alkenylene of 2 to 10 carbons; alkyleneoxy of 2 to 6 carbons; cycloalkylene of 3 to 7 carbons; cycloalkylene of 3 to 7 carbons substituted with a member selected from the group consisting of alkyl of 1 to 7 carbons, an alkoxy of 1 to 7 carbons, an alkylene of 1 to 10 carbons, and an alkenyl of 2 to 7 carbons; cycloalkenylene of 4 to 7 carbons; cycloalkenylene of 4 to 7 carbons substituted with an alkyl of 1 to 7 carbons, an alkoxy of 1 to 7 carbons, an alkylene of 1 to 10 carbons, and an alkenyl of 2 to 7 carbons; arylene; and arylene substituted with an alkyl of 1 to 7 carbons, an alkoxy of 1 to 7 carbons, an alkylene of 1 to 10 carbons, an alkenyl of 2 to 7 carbons; and wherein a is 0 to 1; b is 2 to 6; m is greater than 10; n is greater than 10; and at least one of R<sub>1</sub>, a, and b in mer I is different than R<sub>1</sub>, a, and b in mer II; and wherein:

- 1      □ said composite of at least one polymer and at least one therapeutic  
 2      substance when in operation bioerodes and releases said at least one  
 3      therapeutic substance at a rate selected from (1) a zero order rate, (2) a  
 4      continuous rate, and (3) a variable rate, which rate is produced by  
 5      preselecting said composite of at least one polymer and at least one  
 6      therapeutic substance, and said elastomer to give the desired result.

7  
 8      59. The drug eluting stented graft of claim 53, wherein said at least one polymer  
 9      is a hydrophobic, bioerodible, terpolymer comprising mers I, II, and III  
 10      according to the following formula:



14      wherein:

- 15      □  $R_1$  is a member selected from the group consisting of alkylene of 1 to  
 16      10 carbons; alkenylene of 2 to 10 carbons; alkyleneoxy of 2 to 6  
 17      carbons; cycloalkylene of 3 to 7 carbons; cycloalkylene of 3 to 7  
 18      carbons substituted with a member selected from the group consisting  
 19      of alkyl of 1 to 7 carbons, alkoxy of 1 to 7 carbons, an alkylene of 1 to  
 20      10 carbons, and an alkenyl of 2 to 7 carbons; cycloalkenylene of 4 to 7  
 21      carbons; cycloalkenylene of 4 to 7 carbons substituted with an alkyl of  
 22      1 to 7 carbons, an alkoxy of 1 to 7 carbons, an alkylene of 1 to 10  
 23      carbons, and an alkenyl of 2 to 7 carbons; arylene; and arylene

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1 substituted with an alkyl of 1 to 7 carbons, an alkoxy of 1 to 7 carbons,  
2 an alkylene of 1 to 10 carbons, an alkenyl of 2 to 7 carbons; and  
3 wherein a is 0 to 1; b is 2 to 6; m is greater than 10; n is greater than  
4 10; p is greater than 10; and at least one of R<sub>1</sub>, a, and b in mers I, II  
5 and III is different than R<sub>1</sub>, a, and b in mers I, II and III; and wherein:

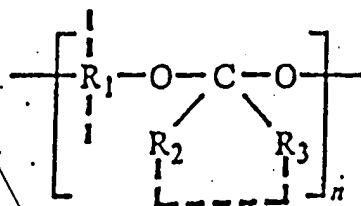
- 6
- 7 □ said composite of at least one polymer and at least one therapeutic  
8 substance when in operation bioerodes and releases said at least one  
9 therapeutic substance at a rate selected from (1) a zero order rate, (2)  
10 a continuous rate, and (3) a variable rate, which rate is produced by  
11 preselecting said composite of said at least one polymer and said at  
12 least one therapeutic substance, and said elastomer to give the  
13 desired result.

14

15 60. The drug eluting stented graft of claim 53, wherein:

- 16 □ a multiplicity of microcapsules is dispersed within said at least one  
17 polymer, wherein said microcapsules have a wall formed of a drug  
18 release rate controlling material;  
19 □ said at least one therapeutic substance is contained within said  
20 multiplicity of microcapsules; and,  
21  
22 □ said at least one polymer has the formula:  
23



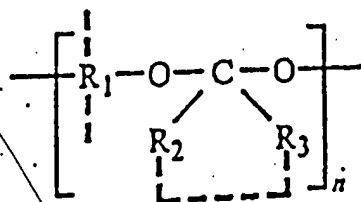


wherein  $\text{R}_1$  is a member selected from the group of divalent, trivalent and tetravalent radicals consisting of alkylene of 1 to 10 carbons; alkenylene of 2 to 10 carbons; alkyleneoxy of 2 to 6 carbons; cycloalkylene of 3 to 7 carbons; cycloalkylene of 3 to 7 carbons substituted with an alkyl of 1 to 7 carbons, alkoxy of 1 to 7 carbons, an alkylene of 1 to 10 carbons, and an alkenyl of 2 to 7 carbons; cycloalkenylene of 4 to 7 carbons; cycloalkenylene of 4 to 7 carbons substituted with an alkyl of 1 to 7 carbons, an alkoxy of 1 to 7 carbons, an alkylene of 1 to 10 carbons, and an alkenyl of 2 to 7 carbons; arylene, and arylene substituted with an alkyl of 1 to 7 carbons, an alkoxy of 1 to 7 carbons, and an alkenyl of 2 to 7 carbons;  $\text{R}_2$  and  $\text{R}_3$  are selected from the group consisting of alkyl of 1 to 7 carbons; alkenyl of 2 to 7 carbons; alkoxy of 1 to 7 carbons; alkenyloxy of 2 to 7 carbons; alkylene of 2 to 6 carbons; alkenylene of 3 to 6 carbons; alkyleneoxy of 2 to 6 carbons; alkenyleneoxy of 3 to 6 carbons; aryloxy; aralkyleneoxy of 8 to 12 carbons; aralkenyleneoxy of 8 to 12 carbons; oxa;  $\text{OR}_1\text{O}$  with  $\text{R}_1$  as defined above; a heterocyclic ring of 5 to 8 carbon and oxygen atoms formed when  $\text{R}_2$  and  $\text{R}_3$  are taken together; a heterocyclic ring of 5 to 8 carbon and oxygen atoms substituted with an alkyl of 1 to 7 carbons, an alkoxy of 1 to 7 carbons and alkenyl of 2 to 7 carbons formed

1 when  $R_2$  and  $R_3$  are taken together; a fused polycyclic ring of 8 to 12  
2 carbon and oxygen atoms formed when  $R_2$  and  $R_3$  are taken together; a  
3 fused polycyclic ring of 8 to 12 carbon and oxygen atoms substituted with  
4 an alkyl of 1 to 7 carbons; an alkoxy of 1 to 7 carbons and an alkenyl of 2  
5 to 7 carbons; and wherein at least one of said  $R_2$  and  $R_3$  is a member  
6 selected from the group consisting of alkoxy, alkenyloxy and  $OR_1O$ ;  $R_2$   
7 and  $R_3$  when taken together are a member selected from the group of  
8 heterocyclic and fused polycyclic rings having at least one oxygen atom in  
9 the ring; and wherein  $n$  is greater than 10;  
10 so that, in operation, said polymer and said microcapsules bioerode at a  
11 controlled and continuous rate over a prolonged period of time, thereby releasing  
12 said at least one therapeutic substance at a controlled and continuous rate over  
13 a prolonged period of time.

14  
15 61. The drug eluting stented graft of claim 53, wherein:

- 16 ☐ said coat further comprises at least a first layer and a second layer,  
17 wherein said first layer comprises said at least one therapeutic  
18 substance and at least a first polymer, and said second layer  
19 comprises said at least one therapeutic substance and at least a  
20 second polymer, wherein at least one of said first polymer and said  
21 second polymer are selected from the group consisting of polymers of  
22 the formula:  
23



wherein  $R_1$  is a member selected from the group of divalent, trivalent and tetravalent radicals consisting of alkylene of 1 to 10 carbons; alkenylene of 2 to 10 carbons; alkyleneoxy of 2 to 6 carbons; cycloalkylene of 3 to 7 carbons; cycloalkylene of 3 to 7 carbons substituted with an alkyl of 1 to 7 carbons, alkoxy of 1 to 7 carbons, alkylene of 1 to 10 carbons, and an alkenyl of 2 to 7 carbons; cycloalkenylene of 4 to 7 carbons; cycloalkenylene of 4 to 7 carbons substituted with an alkyl of 1 to 7 carbons, an alkoxy of 1 to 7 carbons, an alkylene of 1 to 10 carbons, and an alkenyl of 2 to 7 carbons; arylene; and arylene substituted with an alkyl of 1 to 7 carbons, an alkoxy of 1 to 7 carbons, and an alkenyl of 2 to 7 carbons;  $R_2$  and  $R_3$  are selected from the group consisting of alkyl of 1 to 7 carbons; alkenyl of 2 to 7 carbons; alkoxy of 1 to 7 carbons; alkenyloxy of 2 to 7 carbons; alkylene of 2 to 6 carbons; alkenylene of 3 to 6 carbons; alkyleneoxy of 2 to 6 carbons; alkenyleneoxy of 3 to 6 carbons; aryloxy; aralkyleneoxy of 8 to 12 carbons; aralkenyleneoxy of 8 to 12 carbons; oxa;  $O R_1 O$  with  $R_1$  as defined above; a heterocyclic ring of 5 to 8 carbon and oxygen atoms

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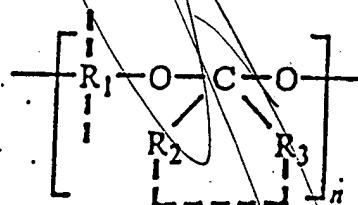
1 formed when  $R_2$  and  $R_3$  are taken together; a heterocyclic ring of  
2 5 to 8 carbon and oxygen atoms substituted with an alkyl of 1 to 7  
3 carbons; an alkoxy of 1 to 7 carbons and an alkenyl of 2 to 7 carbons  
4 formed when  $R_2$  and  $R_3$  are taken together; a fused polycyclic  
5 ring of 8 to 12 carbon and oxygen atoms formed when  $R_2$  and  $R_3$   
6 are taken together; a fused polycyclic ring of 8 to 12 carbon and oxygen  
7 atoms substituted with an alkyl of 1 to 7 carbons, an alkoxy of 1 to 7  
8 carbons and an alkenyl of 2 to 7 carbons; and wherein at least one of said  
9  $R_2$  and  $R_3$  is a member selected from the group consisting of alkoxy, alkenyloxy  
10 and  $OR_1O$ ;  $R_1$  and  $R_3$  when taken together are a member selected from the  
11 group of heterocyclic and fused polycyclic rings having at least one oxygen atom  
12 in the ring; and wherein is greater than 10;  
13 so that when in operation, said layers bioerode at a controlled and continuous  
14 rate over a prolonged period of time, thereby releasing said at least one  
15 therapeutic substance at a controlled and continuous rate over a prolonged  
16 period of time.

17  
18 62. The drug eluting stented graft of claim 61, wherein said first polymer is a  
19 pharmaceutically acceptable biocompatible non-bioerodible polymer that  
20 sequesters an agent for brachytherapy.  
21

63. The drug eluting stented graft of claim 62, wherein said agent for brachytherapy is selected from the group consisting of palladium-103 ( $^{103}\text{Pd}$ ),  $^{192}\text{Ir}$ ,  $^{32}\text{P}$ ,  $^{188}\text{Re}$ , and Sr/Y90 source trains.

64. The drug eluting stented graft of claim 53, wherein:

- a multiplicity of discrete, closed cells exists within said at least one polymer, said cells having a wall formed and defined by said at least one polymer;
- said at least one polymer has the formula:



wherein  $R_1$  is a member selected from the group of divalent, trivalent and tetravalent radicals consisting of alkylene of 1 to 10 carbons; alkenylene of 2 to 10 carbons; alkyleneoxy of 2 to 6 carbons; cycloalkylene of 3 to 7 carbons; cycloalkylene of 3 to 7 carbons substituted with an alkyl of 1 to 7 carbons, alkoxy of 1 to 7 carbons, an alkylene of 1 to 10 carbons, and an alkenyl of 2 to 7 carbons; cycloalkenylene of 4 to 7 carbons; cycloalkenylene of 4 to 7 carbons substituted with an alkyl of 1 to 7

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carbons, an alkoxy of 1 to 7 carbons, an alkylene of 1 to 10 carbons, and an alkenyl of 2 to 7 carbons; arylene; and arylene substituted with an alkyl of 1 to 7 carbons, an alkoxy of 1 to 7 carbons, and an alkenyl of 2 to 7 carbons;  $R_2$  and  $R_3$  are selected from the group consisting of alkyl of 1 to 7 carbons; alkenyl of 2 to 7 carbons; alkoxy of 1 to 7 carbons; alkenyloxy of 2 to 7 carbons; alkylene of 2 to 6 carbons; alkenylene of 3 to 6 carbons; alkyleneoxy of 2 to 6 carbons; alkenyleneoxy of 3 to 6 carbons; aryloxy; aralkyleneoxy of 8 to 12 carbons; aralkyleneoxy of 8 to 12 carbons; oxa;  $OR_1O$  with  $R_1$  as defined above; a heterocyclic ring of 5 to 8 carbon and oxygen atoms formed when  $R_2$  and  $R_3$  are taken together; a heterocyclic ring of 5 to 8 carbon and oxygen atoms substituted with an alkyl of 1 to 7 carbons, an alkoxy of 1 to 7 carbons and an alkenyl of 2 to 7 carbons formed when  $R_2$  and  $R_3$  are taken together; a fused polycyclic ring of 8 to 12 carbon and oxygen atoms formed when  $R_2$  and  $R_3$  are taken together; a fused polycyclic ring of 8 to 12 carbon and oxygen atoms substituted with an alkyl of 1 to 7 carbons, an alkoxy of 1 to 7 carbons and an alkenyl of 2 to 7 carbons; and wherein at least one of said  $R_2$  and  $R_3$  is a member selected from the group consisting of alkoxy, alkenyloxy and  $OR_1O$ ;  $R_2$  and  $R_3$  when taken together are a member selected from the group of heterocyclic and fused polycyclic rings having at least one oxygen atom in the ring; and wherein  $n$  is greater than 10;

□ wherein said at least one therapeutic substance dissolved in a pharmaceutically acceptable carrier that is a solvent for said at least

1 one therapeutic substance and a nonsolvent for said at least one  
2 polymer is contained within said multiplicity of discrete, closed cells;  
3 so that, when in operation, said at least one polymer is capable of bioeroding at a  
4 controlled and continuous rate over a prolonged period of time, thereby releasing  
5 said at least one therapeutic substance at a controlled and continuous rate over  
6 a prolonged period of time.

7  
8 65. The drug eluting stented graft of claim 53, wherein said stent comprises a  
9 plurality of elements, wherein each said element comprises an undulating  
10 linear shape formed into a generally cylindrical configuration having a cylinder  
11 axis generally aligned on the axis of said hollow bore, and wherein each said  
12 element is connected to an adjacent neighbor element by at least one linear  
13 connector.

14  
15 66. The drug eluting stented graft of claim 65, wherein said plurality of elements  
16 comprises a spiral.

17  
18 67. The drug eluting stented graft of claim 65, wherein at least one said connector  
19 is substantially circumferentially offset from an adjacent neighbor connector.

20  
21 68. The drug eluting stented graft of claim 67, wherein said circumferentially  
22 offset connectors form a helical array.

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23

69. The drug eluting stented graft of claim 65, wherein at least one said connector is not substantially circumferentially offset from an adjacent neighbor connector.

70. The drug eluting stented graft of claim 65, wherein said undulating linear shape is a generally zigzag shape comprising a plurality of zigs having tips and a plurality of zags having tips, wherein said tip of each said zig of each element and the nearest said tip of each said zig of an adjacent neighbor element generally lie in a plane passing through the axis of said hollow bore, and wherein said tip of at least one said zig of each element and at least one said nearest said tip of a zig of an adjacent neighbor are connected by one said linear connector.

71. The drug eluting stented graft of claim 65, wherein said undulating linear shape is a sinusoidal shape having a plurality of peaks and a plurality of valleys, wherein each said peak of each element and each said valley of an adjacent neighbor generally lie in a plane passing through the axis of said hollow bore, and wherein at least one said peak of each element and said valley of an adjacent neighbor lying generally in said plane are connected by one said linear connector.

72. The drug eluting stented graft of claim 65, wherein each said linear connector has a length dimension generally parallel to the axis of said hollow bore, and

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1 a width and depth dimension, and wherein said length dimension is greater  
2 than said width dimension and said length dimension is greater than said  
3 depth dimension.

73. The drug eluting stented graft of claim 72, wherein said length dimension is about 3 to 10 times greater than said width dimension, and said length dimension is about 3 to 10 times greater than said depth dimension.

74. The drug eluting stented graft of claim 53 wherein said PTFE is replaced by an elastomer selected from the group consisting of fluorinated ethylene propylene, polytetrafluoroethylene-perfluoroalkyl vinyl ether copolymer, polyvinyl chloride, polypropylene, polyethylene terephthalate, broad fluoride; and, other biocompatible plastics.

75. The drug eluting stented graft of claim 53 wherein said PTFE covering is formed of expanded, sintered PTFE tape, said tape having been wound about the outer surface of said stent to create said covering thereon.

76. The drug eluting stented graft of claim 53, wherein said PTFE is expanded  
polytetrafluoroethylene having fibrils.

77. The drug eluting stented graft of claim 76, wherein said fibrils measure up to about 300  $\mu$  in length.

1

2 78. The drug eluting stented graft of claim 76, wherein said fibrils measure up to  
3 about 200  $\mu$  in length.

4

5 79. The drug eluting stented graft of claim 76, wherein said fibrils measure up to  
6 about 100  $\mu$  in length.

7

8 80. The drug eluting stented graft of claim 76, wherein said fibrils measure up to  
9 about 50  $\mu$  in length.

10

11 81. The drug eluting stented graft of claim 76, wherein said fibrils measure up to  
12 about 5  $\mu$  in length.

13

14 82. The drug eluting stented graft of claim 75 wherein said tape has a width of  
15 less than about 1 inch (2.54 cm.).

16

17 83. The drug eluting stented graft of claim 75 wherein said tape has a thickness  
18 of less than 0.015 inch (0.038 cm.) and wherein said tape is wound about  
19 said stent in overlapping fashion, such that said elastomer covering  
20 comprises 1 to 10 layers of said tape.

21

22 84. The drug eluting stented graft of claim 75 wherein said tape is helically  
23 wrapped about said stent.

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1

2 85. The drug eluting stented graft of claim 75 wherein said tape has a width of 0.5  
3 inches (1.27 cm), and wherein said tape is helically wrapped such that 6-8  
4 revolutions of tape are applied per longitudinal inch (2.54 cm.) of said drug  
5 eluting stented graft.

6

7 86. The drug eluting stented graft of claim 75 wherein said tape is helically  
8 wrapped alternately in a first direction and then in the opposite direction.

9

10 87. The drug eluting stented graft of claim 86 further comprising 8 layers of said  
11 tape.

12

13 88. The drug eluting stented graft of claim 53 wherein said stent is a self-  
14 expanding stent.

15

16 89. The drug eluting stented graft of claim 88, wherein said self-expanding stent  
17 comprises a shape memory alloy that can alternately exist in a first and a  
18 second crystalline state, wherein said stent assumes a radially expanded  
19 configuration when said shape memory alloy is in said first crystalline state,  
20 and a radially compact configuration when said shape memory alloy is in said  
21 second crystalline state.

22

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1 90. The drug eluting stented graft of claim 53 wherein said stent is a pressure-  
2 expandable stent.

3  
4 91. The drug eluting stented graft of claim 88 wherein said stent is formed of a  
5 metal alloy comprising at least two elements selected from the group  
6 consisting of iron, cobalt, chromium, nickel, titanium, niobium, and  
7 molybdenum.

8  
9 92. The drug eluting stented graft of claim 89 wherein said shape memory alloy  
10 comprises at least about 51% to about 59% nickel and the remainder  
11 comprising titanium.

12  
13 93. The drug eluting stented graft of claim 89 wherein said shape memory alloy  
14 comprises about 0.25% chromium, at least about 51% to about 59% nickel,  
15 and the remainder comprising titanium.

16  
17 94. The drug eluting stented graft of claim 53 wherein said covering has a  
18 thickness of less than 0.1 inch (0.25 cm.).

19  
20 95. The drug eluting stented graft of claim 75 wherein said PTFE tape has a  
21 thickness of less than 0.015 inches (0.038 cm.), said tape being wrapped  
22 about said stent in overlapping fashion so as to form said covering.

23

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1 96. The drug eluting stented graft of claim 75 wherein said PTFE tape has a  
2 density of less than 1.6 g/cc.

3  
4 97. The drug eluting stented graft of claim 75 wherein said covering has a  
5 thickness of less than 0.1 inch (0.25 cm.) and the PTFE tape has a density of  
6 less than 1.6 g/cc.

7  
8 98. The drug eluting stented graft of claim 53 wherein said coat was  
9 applied to said stent by the steps of:

- 10 ☐ immersing said stent in a liquid polymer dispersion;  
11 ☐ removing said stent from said liquid polymer dispersion; and,  
12 ☐ drying said liquid polymer dispersion that has remained on said stent,  
13 whereby said coat is formed on said stent.

14  
15 99. The drug eluting stented graft of claim 53 wherein said coat is formed by  
16 electron beam deposition.

17  
18 100. The drug eluting stented graft of claim 53 wherein said tubular covering is  
19 adherent to said coat.

20  
21 101. A method for the treatment of cardiovascular disease, comprising  
22 implanting the drug eluting stented graft of claim 53 in a patient in need of

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1 such treatment wherein said implantation is effective to ameliorate one or  
2 more of the symptoms of said cardiovascular disease.

3

4 102. An article of manufacture, comprising packaging material and the drug  
5 eluting stented graft of claim 53 contained within the packaging material,  
6 wherein said drug eluting stented graft is effective for implantation in a patient  
7 afflicted with cardiovascular disease, and the packaging material includes a  
8 label that indicates that said device is effective for said implantation.

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